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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,704	01/18/2002	Steven M. Ruben	PZ039P1C1	8649

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,704	RUBEN ET AL.,	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,20,24-47,49-52 and 54-56* is/are pending in the application.

4a) Of the above claim(s) *19,20 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-47,49-52 and 54-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *19,20,24-47,49-52 and 54-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED OFFICE ACTION

Applicant's amendment filed on 03 October 2003 is acknowledged and entered. Following the amendment, claims 11, 12, 48 and 53 are canceled, and claims 47 and 52 are amended.

Currently, claims 19, 20, 24-47, 49-52, and 54-56 are pending, and claims 25-47, 49-52, and 54-56 are under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 11, 12, 48 and 53 are moot as the applicant has canceled the claims.

The enablement rejection of claims 31-34, 42-46, 52, and 54-56 under 35 U.S.C. 112, first paragraph, as lack of proper deposit statement is withdrawn in view of applicant's statement in the response.

The prior art rejections of claims 47, 49-52, and 54-56 made in the last Office Action (paper No. 6) are withdrawn in view of applicant's amendment.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-47, 49-52, and 54-56 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by a credible, substantial, and specific, or a well-established utility, for the reasons of record set forth in the last Office Action, paper No. 6, mailed on 03 July 2003, at pages 3-4.

Applicants argument filed on 03 October 2003 has been fully considered, but is not deemed persuasive for reasons below.

At pages 7-8 of the response, the applicant argues that according to MPEP, an applicants assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility

requirement of 35 U.S.C. 101, and Office personal should not begin by questioning the truth of the statement, that according to the Federal Circuit, the threshold of utility is not high: a invention is "useful" under section 101 if it is capable of providing some identifiable benefit, and that the burden is on the Examiner, and the Examiner must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. This argument is not persuasive because the MPEP citations are from "Evaluating the *credibility* of an asserted utility", which is not the issue of the present rejection. The main issue is that the presently asserted utility is not substantial for the reasons addressed in the last Office Action.

At pages 8-9 of the response, the applicant further argues that it is stated that the claimed protein is expressed primarily in ovarian tumor (page 82, line 30), and thus would be predictive of ovarian cancer, and that the claimed polypeptide can be used to generate antibodies useful for identification of ovarian tissue, and ovarian cancer; that MPEP states that the material need only have a stated correlation to predisposition to a disease, not that such a correlation must be confirm by experimentation; that the general rule is that the treatment of specific disease or conditions meet the criteria of 35 U.S.C. 101 (Utility Guidelines); and that one skilled in the art would more likely than not conclude that the claimed polypeptides are useful as a marker for ovarian cancer, and the Examiner has not provide evidence to rebut applicants substantial assertion of utility. This argument is not persuasive for the following reasons. With respect to the statement in the specification (page 82, line 30), pointed out by the applicant, that "that this gene is expressed primarily in ovarian tumor", the Examiner notices that it is for the protein having SEQ ID NO:256 (43 amino acid residues) encoded by gene No. 29 (page 82). However, the HOFND85 has an amino acid sequence of SEQ ID NO:125 (627 amino acid residues), and is also encoded by gene No:29, according to Table 1 on page 162. The sequence search has been conducted using SEQ ID NO:125. As such, the support for the protein having SEQ ID NO:256 cannot be used to support the asserted utility for the HOFND85 protein of SEQ ID NO:125. Applicants are required to clarify this matter. Further, there is no expression data for the HOFND85 of SEQ ID NO:125 in Table 2, and therefore, the specification does not even disclose that the HOFND85 of SEQ ID NO:125 is expressed in ovarian cancer.

Further, even if the cited statement were for the HOFND85 of SEQ ID NO:125, given the other statement in the specification indicating that this protein is also expressed in normal ovarian tissue, implicating a role in normal ovarian function, and potential usefulness in the treatment of female infertility, or as a female contraceptive (page 84, lines 22-25), it is unclear how the claimed polypeptide can be used as an ovarian cancer marker. One skilled in the art would not be able to conclude that the claimed polypeptides are useful as a marker for ovarian cancer in the absence of further evidence, such as elevated levels of the HOFND85 in ovarian cancer in comparison to that in the normal ovarian tissue. The specification fails to provide such, and significant further research and experimentation are required in order to determine whether the HOFND85 is indeed predictive of ovarian cancer. These further research and experimentation, however, is part of the act of invention, and until it has been undertaken, the claimed invention is not considered substantial.

With respect to a stated correlation to predisposition to a disease by MPEP, the present specification merely indicates the *presence* of the claimed polypeptide in ovarian cancer tissue, and asserts it would be useful for the diagnosis. The term "predisposition" means a latent susceptibility to disease, which may be activated under certain conditions (Dorland's Illustrated Medical Dictionary, 29th ed., W.B. Saunders Company, page 1450). However, the present specification never establishes nor states a correlation of the HOFND85 to a *predisposition to the onset* of the ovarian cancer. Even if HOFND85 were elevated in ovarian cancer, it would not be predictable that it is elevated *before* cell transformation.

With respect to that the general rule is that the treatment of specific disease or conditions meet the criteria of 35 U.S.C. 101 by the Utility Guidelines, it does not apply in the instant situation as the claimed invention is not directed to the treatments of specific diseases or conditions, rather, it is directed to an isolated protein or the composition thereof, which is present in ovarian cancer tissue according to one sample analysis, and has no association with the treatment of any disease or condition based on the present disclosure.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-47, 49-52, and 54-56 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons of record set forth in the last Office Action, paper No. 6, at page 5.

Applicants argument filed on 03 October 2003 has been fully considered, but is not deemed persuasive for reasons above.

Furthermore, even if there were utility and enablement of the HOFND85 of SEQ ID NO:125, enablement would remain not being commensurate in scope with claims encompassing the % variants (claims 37-46, for example) and fragments (47, 49-52, and 54-56, for example) of SEQ ID NO:125 or of the polypeptide encoded by the cDNA PTA-1544, for the reasons of record set forth in the last Office Action, paper No. 6, at page 5.

Applicants argument filed on 03 October 2003 has been fully considered, but is not deemed persuasive for reasons below.

At page 10 of the response, the applicant argues that the Federal Circuit has held that making the claimed species and screening them for function is acceptable, as long as the experimentation is not undue; that it is clearly not per se undue to make and test several fragments when specific guidance was clearly disclosed in the specification coupled with what was known in the art at the time the invention was filed; and that it was routine to determine that particular variants of HOFND85 protein exhibit either the tissue distribution or the antigenicity. This argument has been fully considered, but is not persuasive because the issue is not whether a skilled artisan would be able to make and screen for function of the % variants and fragments of the HOFND85 of SEQ ID NO:125, rather, the issue is that the specification does not disclose any specific biological function associated with the protein, and thus the skilled artisan would not be able to make the HOFND85 variants or fragments, and test them for function. Further, a skilled artisan would not know how to use the variants or fragments of the HOFND85 of SEQ ID NO:125, which are not active as no functional limitation associated with the claimed variants

or fragments in the claims, or which do not possess specific antigenicity of SEQ ID NO:125. Therefore, it would require undue experimentation prior to practicing the claimed invention.

Claims 37-47, 49-52, and 54-56 remain further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the last Office Action, paper No. 6, at pages 6-7.

Applicants argument filed on 03 October 2003 has been fully considered, but is not deemed persuasive for reasons below.

At pages 11-12 of the response, the applicant argues that according to Federal Circuit, the written description requirement does not require the applicant to describe exactly the subject matter claimed, and the issue is whether one of skill in the art could derive the claimed ranges from the patent's disclosure; that the specification indeed provided adequate written description to enable one of skill in the art to make useful predictions as to the positions or identities of the claimed polypeptides and to visualize the identity of the members of the genus; and that the Examiner has not met the burden of presenting evidence or reasons why one skilled in the art would not reasonably conclude applicants possession of the subject matter. This argument is not persuasive for the following reasons. The Examiner acknowledges that the written description requirement does not require to describe exactly the subject matter claimed, and the written description requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure. See *Enzo Biochem*, 296 F.3d at 1324, 63 USPQ2d at 1613. However, it is not the case in the instant situation. The present specification discloses a polypeptide sequence of a previously unknown protein, and fails to disclose any specific biological function associated with the protein. Written description of the detailed chemical structure of the encompassed variants and fragments of the HOFND85 of SEQ ID NO:125 is particularly important in absence of a specific known activity because one of skill in the art would have no basis to derive the claimed ranges (variants and fragments in the instant invention) from the patent's disclosure,

and thus, would not be able to envision the detailed chemical structure of the encompassed, or to make any meaningful predictions of the useful variants and fragments of the protein. Therefore, the specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed", and does not conveys to one of ordinary skill in the art as the time of filing that the applicant invented the subject matter as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 35, 40, 45, 50 and 55 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth in the last Office Action, paper No. 6, at page 9.

Applicants argument filed on 03 October 2003 has been fully considered, but is not deemed persuasive for reasons below.

At page 14 of the response, the applicant argues that a "pharmaceutical acceptable carrier" is defined in the specification, page 451, lines 29-31, that it is impermissible in law to require a claim to describe the invention, and that the first paragraph of 35 U.S.C. 112 applies only to the disclosure of the specification, not to the claims. This argument is not persuasive because the rejection is under 35 U.S.C. 112, second paragraph, not first paragraph, and the Examiner does not require the claims to recite the definition of the term from the specification. Additionally, a definition for a "pharmaceutical acceptable carrier" cannot be used to define "an *acceptable* carrier", which is used in the claims, because they are not equivalents and have different scope of meanings. The issue is it is unclear what it is acceptable for, i.e., pharmaceutically acceptable, or something else.

Conclusion:

No claim is allowed.

Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
12/9/03